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FEB 5 2013

510(k) Summary of Safety and Effectiveness

SUBMITTER:	Covidien, Formerly US Surgical A Division of Tyco Healthcare 60 Middletown Avenue North Haven, CT 06473 Tel. No.: (203) 492-5284
CONTACT PERSON:	Mary Mellows Senior, Regulatory Specialist
DATE PREPARED:	September 7, 2012
TRADE/PROPRIETARY NAME:	ReliaMax™ Gastrointestinal Anastomosis Stapler and Reload
COMMON/USUAL NAME:	Surgical Stapler with Implantable Staples
CLASSIFICATION NAME:	Staples, Implantable
PREDICATE DEVICE(S):	DST™ Series GIA™ Staplers (K111825)
DEVICE DESCRIPTION:	Reusable surgical stapler with a single use reload
INTENDED USE:	For Stapler: The reusable staplers have applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis. They may be used for transection and resection of the pancreas. For Reload: The ReliaMax™ single use gastrointestinal anastomosis reload when used with ReliaMax™ reusable gastrointestinal anastomosis stapler have applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis. They may be used for transection and resection of the pancreas.
TECHNOLOGICAL CHARACTERISTICS:	The ReliaMax™ Gastrointestinal Anastomosis Staplers and Reloads are substantially equivalent to the predicate device (K111825) with regard to the stapling technologies. The ReliaMax™ Gastrointestinal Anastomosis Staplers will be available in sizes that are encompassed by the predicate (K111825), 60mm and 80mm lengths. ReliaMax™ Reloads will be provided in three staple sizes, similar to the predicate (K111825) to accommodate various tissue thicknesses: 2.5mm, 3.8mm, and 4.8mm. Identical to the predicate (K111825), ReliaMax™ Reloads will place two double rows of titanium staples and simultaneously cut and divide tissue between the two double rows.
MATERIALS:	All components of ReliaMax™ Gastrointestinal Anastomosis Staplers and Reloads are comprised of materials that are in accordance with ISO Standard 10993-1.

The materials used in the design of the Reliamax™ are identical to the materials in the DST™ Series GIA™ disposable stapler, with one exception. The Reliamax™ also includes a plastic material, which is not used in the DST series GIA™ disposable stapler. All performance stability and biocompatibility testing was conducted using this material with acceptable results.

PERFORMANCE DATA:

In vitro and in vivo performance evaluations were conducted to demonstrate that ReliaMax™ Gastrointestinal Anastomosis Staplers and Reloads are safe and effective and that they perform as intended.

In vitro and in vivo testing to support the intended use of this device includes:

- Firing and Retraction Force
- Clamping and Unclamping Force
- Staple Formation Verification
- Hemostasis
- Burst Strength
- Lung Air Leak
- Lifecycle Reliability Test

The results of this testing demonstrates that the ReliaMax™ Gastrointestinal Anastomosis Staplers and Reloads are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Covidien, Formerly US Surgical Division of Tyco Healthcare
% Ms. Mary Mellows
Senior Regulatory Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

March 15, 2013

Re: K122781
Trade/Device Name: Reliamax™ Gastrointestinal Anastomosis and Reload
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: January 10, 2013
Received: January 28, 2013

Dear Ms. Mellows:

This letter corrects our substantially equivalent letter of February 5, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications For Use

510(k) Number (if known): K122781

Device Name: ReliaMax™ Gastrointestinal Anastomosis Stapler and Reload

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K122781